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K010871

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Donna A. Wolf
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: March 22, 2001

Name of Product: TGL Flex® Reagent Cartridge

FDA Classification Name: Triglyceride Test System

Predicate Device: TRIG Flex® reagent cartridge (K861700)

Device Description: The TGL Flex® reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of triglycerides in serum and plasma.

The triglycerides method is based on an enzymatic procedure in which a combination of enzymes are employed for a bichromatic endpoint measurement of serum triglycerides. The sample is incubated with lipoprotein lipase (LPL) enzyme reagent that converts triglycerides into free glycerol and fatty acids. Glycerol kinase (GK) catalyzes the phosphorylation of glycerol by adenosine-5-triphosphate (ATP) to glycerol-3-phosphate. Glycerol-3-phosphate-oxidase oxidizes glycerol-3-phosphate to dihydroxyacetone phosphate and hydrogen peroxide (H_2O_2). The catalytic action of peroxidase (POD) forms quinoneimine from H_2O_2, aminoantipyrine and 4-chlorophenol. The change in absorbance due to the formation of quinoneimine is directly proportional to the total amount of glycerol and its precursors in the sample and is measured using a bichromatic (510, 700 nm) endpoint technique.

$$\text{Triglycerides} \xrightarrow{\text{LPL}} \text{Glycerol + Fatty Acids}$$

$$\text{Glycerol + ATP} \xrightarrow{\text{GK}} \text{Glycerol-3-Phosphate + ADP}$$

$$\text{Glycerol-3-Phosphate + } O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyacetone phosphate + } H_2O_2$$

$$2\,H_2O_2 + \text{Aminoantipyrine + 4-Chlorophenol} \xrightarrow{\text{POD}} \text{Quinoneimine + HCL + 4 } H_2O$$

Intended Use: The TGL Flex® reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of triglycerides in serum and plasma.

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Comparison to Predicate Device:

Item	TGL Flex® Reagent	TRIG Flex® Reagent
Sample Type	Serum and plasma	Serum and plasma
Methodology	Enzymatic	Enzymatic
Detection	Bichromatic endpoint (510, 700 nm)	Bichromatic rate (340, 383 nm)

Conclusion: Split sample comparison between the TGL Flex® reagent cartridge and the TRIG Flex® reagent cartridge gave a correlation coefficient of 0.999, slope of 1.01, and an intercept of -4.17 mg/dL when tested with 230 clinical patient samples ranging from 30 to 906 mg/dL (see Attachment C).

Donna A. Wolf
Regulatory Affairs Specialist
Date: March 22, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Donna A. Wolf
Regulatory Affairs Specialist
Dade Behring, Inc.
514 GBC Drive
Newark, Delaware 19702

Re: K010871
Trade Name: TGL Flex® Reagent Cartridge
Regulation Number: 21 CFR § 862.1705
Regulatory Class: I
Product Code: CDT
Dated: June 4, 2001
Received: June 5, 2001

Dear Ms. Wolf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name: TGL Flex® Reagent Cartridge

Indications for Use:

The TGL Flex® reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of triglycerides in serum and plasma. Measurements obtained are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010871

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)